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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,088	11/22/2000	Thomas Sai Ying Ko	Q-61930	1770

7590

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EXAMINER

WILLIS, MICHAEL A

ART UNIT

PAPER NUMBER

1619

DATE MAILED: 01/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/717,088

Applicant(s)

KO, THOMAS SAI YING

Examiner

Michael A. Willis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Applicant's amendment of 7 November 2001 is entered. Claims 2, 4, 8, 12, and 19 are amended. Claims 1-21 are pending. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Oath/Declaration

The substitute declaration received in applicant's communication of 7 November 2001 is acknowledged. The substitute declaration corrects the deficiency regarding the citizenship of the inventor as stated in a previous Office Action. The objection to the declaration is withdrawn.

Response to Amendment

The Applicant's response to the rejection of claims 2, 4-6, 8-9, 12 and 19 made by the Examiner in a previous Office Action under 35 U.S.C. 112, second paragraph, fully meets the deficiencies encompassed by said rejection. Therefore, said rejection is hereby withdrawn.

Response to Arguments

Claims 1-3, 10, 11, 13, 15-17, and 20-21 are rejected under 35 USC 102(b) as being anticipated by Driggers et al (US Pat. 5,041,287) for reasons as stated in a previous Office Action. Applicant argues that Driggers does not teach a water-soluble compound as recited in part (c) of Claim 1. Applicant asserts that the physiologically

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active compounds taught by Driggers are soluble in an organic solvent and not water-soluble. The argument is based on the reasoning that Driggers teaches medicaments that "are soluble in the solvent" (see col. 3, lines 8-9) and that the listing of preferred solvents does not mention water, therefore applicant concludes that the medicaments of Driggers are not water soluble.

Applicant's argument has been fully considered, but is not persuasive. It is noted that Driggers teaches, "preferably, the composition includes water" (see col. 2, line 60). Therefore, it would be understood that water-soluble medicaments are not excluded by the statement that medicaments "are soluble in the solvent" as taught by Driggers. More directly, in Example 2, Driggers discloses a composition comprising Lidocaine, the salt of which is water soluble as well as diethanolamine, which is miscible with water (see col. 5, line 45 through col. 6, line 31). Therefore, the rejection is maintained.

Claims 1-21 are rejected under 35 USC 103(a) as being unpatentable over Tipton et al (US Pat. 5,632,727) in view of Modak et al (US Pat. 5,708,023) and Driggers et al (US Pat. 5,041,287) for reasons as stated in a previous Office Action.

Applicant argues that Tipton does not teach water-soluble compounds because any biologically active agents which are present are dissolved in the solvent (col. 2, lines 29-31). Applicant asserts that water-soluble biologically active agents are therefore excluded. The argument has been fully considered, but is not persuasive. Tipton teaches that the biologically-active agent can be miscible in the organic solvent or insoluble in the organic solvent, i.e. water soluble (see col. 8, lines 44-47). Tipton further

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teaches that the release of the biologically active agent from the matrix can be varied by the solubility of the biologically active agent in water (see col. 8, lines 62-65). Finally Tipton teaches the use of water soluble pore-forming agents (see col. 7, lines 34-49). Therefore, Tipton teaches the use of water-soluble biologically active agents.

Applicant argues that Tipton does not teach spray-on skin patch compositions with the same properties upon application to the skin as claimed. Applicant further argues that the method of Tipton requiring is inconvenient and messy. In response, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See MPEP § 2111.02.

Applicant argues that Tipton does not teach the use of a plasticizing agent as described in part (b) of Claim 1 and that Tipton makes no mention of phthalic esters. However, it is noted that column 10, line 56 states "Examples of suitable modifiers include phthalic esters". Tipton teaches that additives can be added to effect mechanical properties of the film (col. 10, lines 47-48) and that such modifiers can be added to increase flexibility (see col. 10, lines 48-49). Therefore, it is the position of the

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examiner that one of ordinary skill in the art would understand that Tipton teaches the use of plasticizers and the use of phthalic esters.

Applicant argues that Modak teaches away from Tipton in that the compositions of Modak are not directed at spray-on skin patch compositions. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant further argues that Modak teaches away from Tipton in that Modak teaches the necessity of including an agent such as a heavy metal salt in combination with agents such as cetrimide and triclosan. It is the position of the examiner that this does not teach away from Tipton in that Tipton is open to the incorporation of a variety of biological agents which does not exclude heavy metals per se, particularly if they increase the effectiveness of the desired biological agent (see col. 9, line 32 through col. 10, line 43).

Applicant argues that Driggers teaches away from Tipton and Modak because the disclosed films are different and incompatible. In response, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the present case, it is

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the position of the examiner that the references suggest to one of ordinary skill in the art that the polymers taught by Driggers are appropriate for application to the skin as sprayable compositions and one of ordinary skill in the art would be motivated to use such polymers due to their non-toxic properties.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael A. Willis whose telephone number is (703) 305-1679. The examiner can normally be reached on Mon. to Fri. from 9 a.m. to 5:30 p.m.

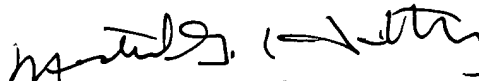
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana L. Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.



Michael A. Willis
Examiner
Art Unit 1619

January 7, 2002



MICHAEL G. HARTLEY
PRIMARY EXAMINER